



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,906	05/14/2001	Steven F. Sukits	37174/8	7599

7590 09/30/2003

Craig J. Arnold
Amster, Rothstein & Ebenstein
90 Park Avenue
New York, NY 10016

EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,906

Applicant(s)

SUKITS ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1631

Part III DETAILED ACTION

Claims 1-36 are currently pending.

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to solution comprising TNF receptor domain (TNFR-1 DD).
- II. Claim 7, drawn to active site of C-TRADD DD binding protein defined by first set of coordinates.
- III. Claim 8, drawn to active site of C-TRADD DD binding protein defined by second set of coordinates.
- IV. Claim 9, drawn to active site of C-TRADD DD binding protein defined by third set of coordinates.
- V. Claim 10, drawn to active site of C-TRADD DD binding protein defined by fourth set of coordinates.
- VI. Claims 15-23, drawn to method of identifying agent that interacts with TNFR-1.
- VII. Claims 25-34, drawn to method of identifying potential inhibitor of TNFR-1.
- VIII. Claim 11, drawn to an agent binding to the site of claim 7.

Art Unit: 1631

- IX. Claim 12, drawn to an agent binding to the site of claim 8.
- X. Claim 13, drawn to an agent binding to the site of claim 9.
- XI. Claim 14, drawn to an agent binding to the site of claim 10.
- XII. Claim 24, drawn to an agent identified by method of Group VI.
- XIII. Claims 35,36 drawn to agent identified by method of Group VII.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-V, VIII-XIII are patentably distinct from each other because of the materially different structures of the compounds they are claiming; each product would be expected to possess distinctly different structure, and/or physico-chemical properties, and/or capable of separate manufacture and/or use.

Inventions VI,VII are related as independent methods which have different modes of operation, different functions, and different effects. Identifying an agent that interacts with certain residues (e.g., water as an agent) does not teach an agent having inhibitory function.

Inventions II-V and VI,VII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

Art Unit: 1631

another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used in a materially different processes, e.g., preparation of antibodies; further, methods VI and VII are alternate methods of using the products of Group II-V.

Agents of Groups VIII-XI and corresponding active sites of Groups II-V are patentably distinct as the agents can be obtained by other methods, e.g., organic synthesis, and the information about active sites can be used for other purposes, e.g., production of antibodies.

Methods VI, VII and corresponding agents of Groups XII, XIII are related as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products can be prepared by methods of organic synthesis.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

Art Unit: 1631

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Species Requirement

Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims.(MPEP 808.01(a))

If Group VII is elected the following election of species is hereby required for the initial search for examination on merits:

Art Unit: 1631

The claims of Group are individually or dependently directed to a plurality of patentably distinct species of active sites, such as those recited in claims 11-14, which will require separate bibliographic, manual and computer search.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone

Serial Number: 09/854906

Page 7

Art Unit: 1631

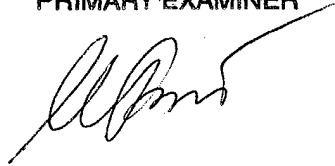
are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

September 19, 2003

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', with a long horizontal stroke extending to the right.